

§ 890.1225

an electrode from a patient to a diagnostic machine.

(b) *Classification*. Class II (special controls). The special controls consist of:

(1) The performance standard under part 898 of this chapter, and

(2) The guidance document entitled "Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables." This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994; 65 FR 19319, Apr. 11, 2000]

§ 890.1225 Chronaximeter.

(a) *Identification*. A chronaximeter is a device intended for medical purposes to measure neuromuscular excitability by means of a strength-duration curve that provides a basis for diagnosis and prognosis of neurological dysfunction.

(b) *Classification*. Class II (performance standards).

§ 890.1375 Diagnostic electromyograph.

(a) *Identification*. A diagnostic electromyograph is a device intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves, and to monitor and display the electrical activity produced by nerves, for the diagnosis and prognosis of neuromuscular disease.

(b) *Classification*. Class II (performance standards).

§ 890.1385 Diagnostic electromyograph needle electrode.

(a) *Identification*. A diagnostic electromyograph needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medical purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle).

(b) *Classification*. Class II (performance standards).

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§ 890.1450 Powered reflex hammer.

(a) *Identification*. A powered reflex hammer is a motorized device intended for medical purposes to elicit and determine controlled deep tendon reflexes.

(b) *Classification*. Class II (performance standards).

§ 890.1575 Force-measuring platform.

(a) *Identification*. A force-measuring platform is a device intended for medical purposes that converts pressure applied upon a planar surface into analog mechanical or electrical signals. This device is used to determine ground reaction force, centers of percussion, centers of torque, and their variations in both magnitude and direction with time.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.1600 Intermittent pressure measurement system.

(a) *Identification*. An intermittent pressure measurement system is an evaluative device intended for medical purposes, such as to measure the actual pressure between the body surface and the supporting media.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996; 66 FR 38816, July 25, 2001]

§ 890.1615 Miniature pressure transducer.

(a) *Identification*. A miniature pressure transducer is a device intended for medical purposes to measure the pressure between a device and soft tissue by converting mechanical inputs to analog electrical signals.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in